

**LEGISLATIVE SERVICES AGENCY  
OFFICE OF FISCAL AND MANAGEMENT ANALYSIS**

200 W. Washington, Suite 301  
Indianapolis, IN 46204  
(317) 233-0696  
<http://www.in.gov/legislative>

**FISCAL IMPACT STATEMENT**

**LS 6379**

**BILL NUMBER: HB 1133**

**NOTE PREPARED: Dec 3, 2003**

**BILL AMENDED:**

**SUBJECT:** Tattoo Dyes and Cosmetics.

**FIRST AUTHOR:** Rep. Budak

**FIRST SPONSOR:**

**BILL STATUS:** As Introduced

**FUNDS AFFECTED: X GENERAL  
DEDICATED  
FEDERAL**

**IMPACT:** State

**Summary of Legislation:** This bill requires the Executive Board of the Department of Health to regulate tattoo dyes. The bill prohibits indelible or temporary tattooing with a dye containing para-phenylenediamine (coal-tar dyes). It also requires the adoption of a rule prohibiting the inclusion of para-phenylenediamine in cosmetics.

**Effective Date:** July 1, 2004.

**Explanation of State Expenditures:** This bill would require the Department of Health to adopt rules regulating dyes, pigments, and inks used in temporary and indelible tattooing. The rules must specifically prohibit the use of para-phenylenediamine, commonly called coal-tar, in dyes, pigments, and inks to be used on or in the skin. The bill further requires the adoption of a rule prohibiting a cosmetic from containing para-phenylenediamine with the exception of coal-tar hair dyes having the required cautionary labeling. The Department of Health reports that the rule promulgation required by this bill can be accomplished within the current level of funding available.

*Background:* The Department of Health currently has a rule in place at 410 IAC1-5-35 concerning indelible tattooing that requires the inks used to be from professional suppliers that specifically provide dyes or pigments for the tattooing of human skin. This rule provides that only nontoxic, sterile materials shall be used for the preparation of tattoo inks or pigments and single-use or individual portions of dyes or pigments in clean, single-use containers shall be used for each patron. The current rule applies to dyes, pigments, or other objects placed under the skin and does not address products used in the application of temporary tattoos, nor does it specifically prohibit the use of para-phenylenediamine in the regulated products. The Department had a rule prohibiting the use of para-phenylenediamine in cosmetics other than coal-tar hair dyes that expired

on January 1, 2002. It has not been re-promulgated. Para-phenylenediamine is a synthetic pigment that is widely used as a hair dye and industrial dye. “It is a potent sensitiser and is the responsible agent in most cases of hairdressing dye allergic contact dermatitis.” (1)

According to the federal Food and Drug Administration (FDA), temporary tattoos include skin decals that are applied to the skin with a moistened piece of cotton. These skin decals contain color additives approved for cosmetic use on the skin and fade several days after application. The FDA has issued an import alert for several foreign-made temporary tattoo decals because they are either not correctly labeled or they contain colors that are not permitted for use in cosmetics applied to the skin. The FDA reports that the Agency has received reports of allergic reactions to temporary skin tattoo decals.

Another type of temporary skin tattooing consists of henna paste applied to the skin as decorative body paintings. Decorative body painting with henna paste, called mehndi, is an ancient cultural practice in the Middle East and Asia. Henna is a naturally occurring plant dye that is usually employed as a hair dye. It is often recommended to individuals who are sensitive to synthetic hair dyes due to its low allergenicity. (The FDA has approved henna only for use as a hair dye, not for direct application to the skin.) Henna paste imparts a reddish brown color to hair and to the skin. It takes many hours for pure henna dye to impregnate the skin. In order to achieve other colors than the natural reddish brown, the henna paste may be mixed with other ingredients, and to shorten the considerable time necessary to impregnate the skin, para-phenylenediamine may be added to shorten the time the paste is left on the skin. These additive agents result in a product referred to as black henna or blue henna; the exact ingredients are often unknown. Although reports of allergic reaction to pure henna are rare, the causative agent in patients developing reactions to black henna tattoos appears to be para-phenylenediamine. There have been reports of allergic reactions to henna tattoos, and the FDA has issued an import alert for several foreign-produced henna products intended for application to the skin because the product appears to be adulterated with color additives that are unsafe.

**Explanation of State Revenues:**

**Explanation of Local Expenditures:**

**Explanation of Local Revenues:**

**State Agencies Affected:** The Department of Health.

**Local Agencies Affected:**

**Information Sources:** Zach Cattell, Legislative Liaison for the Department of Health, 317-233-2170; Food and Drug Administration Import Alerts at [www.fda.gov/ora/fiars/ora\\_import\\_ia5314.html](http://www.fda.gov/ora/fiars/ora_import_ia5314.html) and [www.fda.gov/ora/fiars/ora-import-ia5319.html](http://www.fda.gov/ora/fiars/ora-import-ia5319.html), (1) “Case Report, Contact Dermatitis due to a Henna Tatoo,” P. Carretero, M.M. Garces et.al., *Alergol Immunol Clin* 2000;15:325-327 and “Contact Dermatitis after Temporary Henna Tattoos - An Increasing Phenomenon,” Severin Lauchl, Stephan Lautenschlager, in *Swiss Med Weekly*, 2001; 131: 199-202.

**Fiscal Analyst:** Kathy Norris, 317-234-1360.